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(54) **ANALYTE MONITORING SYSTEM HAVING AN ALERT**

(71) Applicant: **Abbott Diabetes Care Inc.**, Alameda, CA (US)

(72) Inventor: **Wesley Scott Harper**, Alameda, CA (US)

(73) Assignee: **Abbott Diabetes Care Inc.**, Alameda, CA (US)

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See application file for complete search history.

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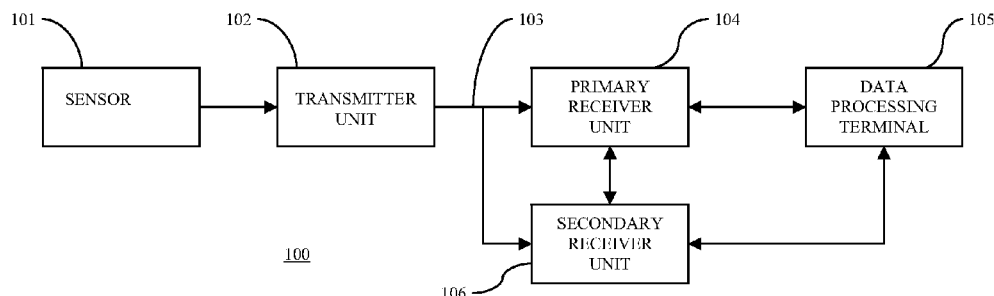
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Primary Examiner — John A Tweel, Jr.
(74) *Attorney, Agent, or Firm* — Jackson & Co., LLP

(57) **ABSTRACT**

Described herein are analyte monitoring systems including a receiver or data processing component that is configured to automatically issue a first alert notification when a first predetermined number of consecutive data packets are not received from the sensor/sensor electronics, and automatically issue a second alert notification when a second predetermined number of consecutive data packets are not received by the sensor/sensor electronics. The receiver may also be configured to enable a user to disenable alert or alarm notifications that are triggered based on detected events.

20 Claims, 5 Drawing Sheets

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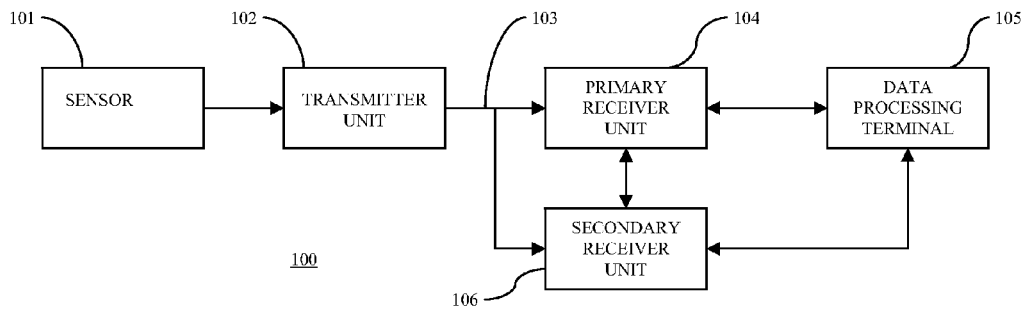
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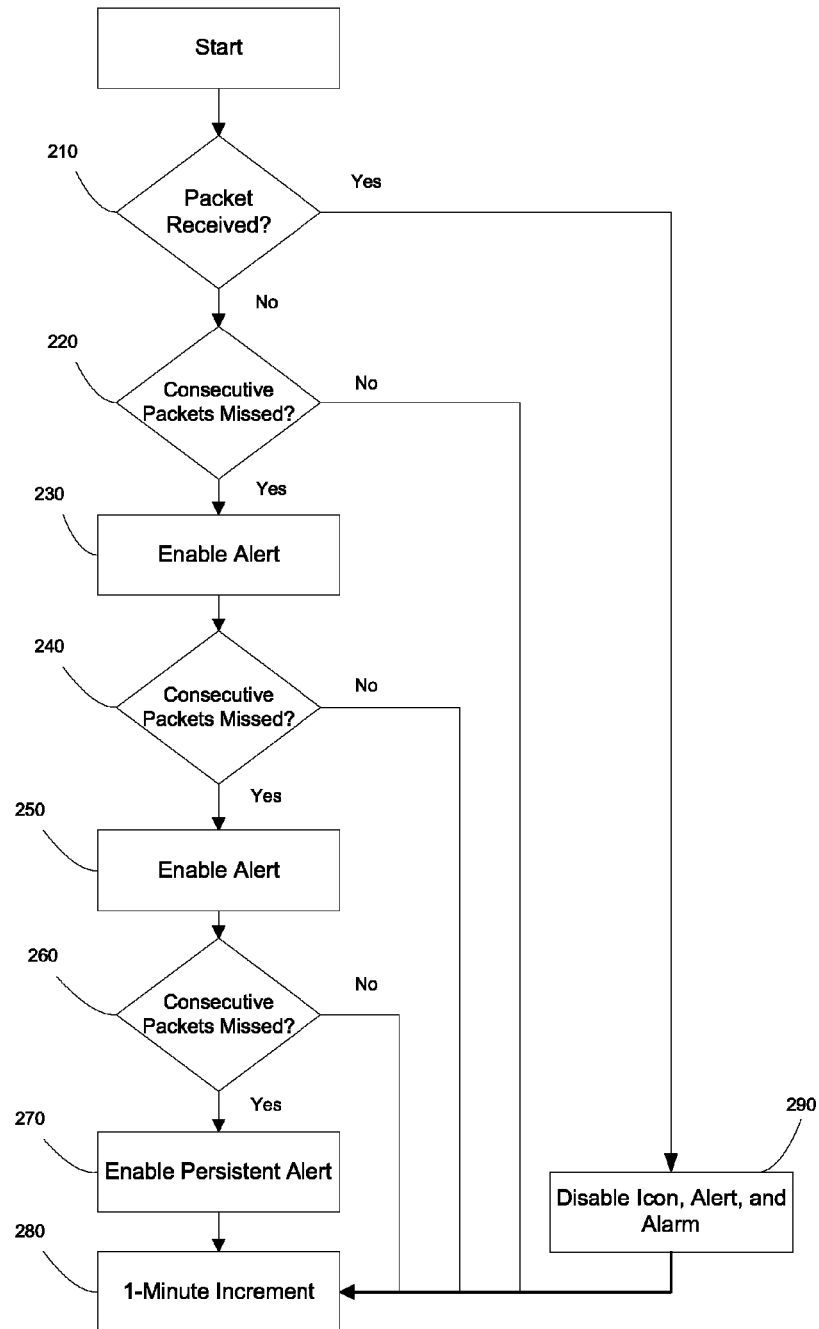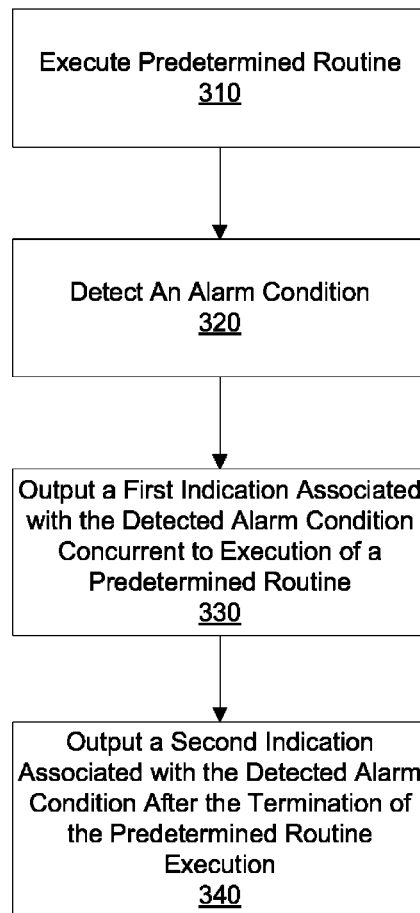
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FIG. 1

Start

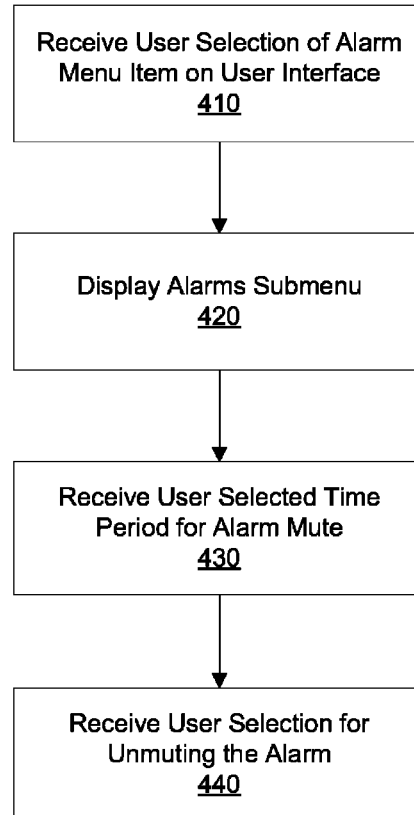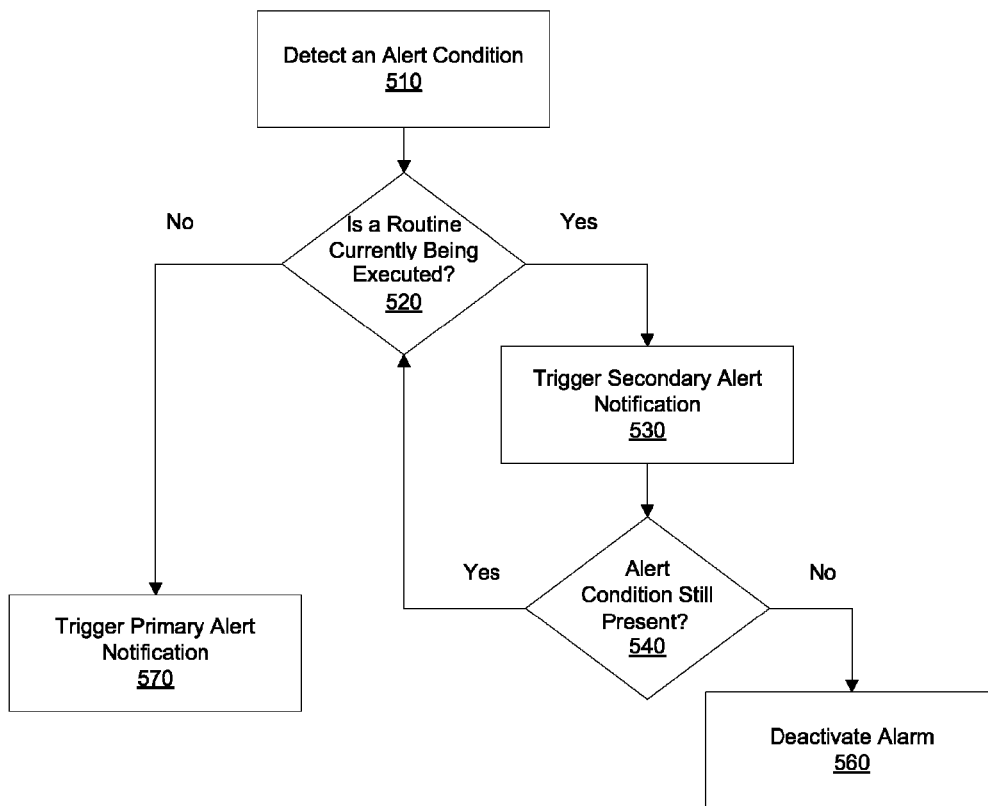210 — Packet Received? — Yes

No

220 — Consecutive Packets Missed? — No

Yes

230 — Enable Alert

240 — Consecutive Packets Missed? — No

Yes

250 — Enable Alert

260 — Consecutive Packets Missed? — No

Yes

270 — Enable Persistent Alert

280 — 1-Minute Increment

290 — Disable Icon, Alert, and Alarm

FIG. 2

Execute Predetermined Routine
310

Detect An Alarm Condition
320

Output a First Indication Associated
with the Detected Alarm Condition
Concurrent to Execution of a
Predetermined Routine
330

Output a Second Indication
Associated with the Detected Alarm
Condition After the Termination of
the Predetermined Routine
Execution
340

FIG. 3

Receive User Selection of Alarm
Menu Item on User Interface
__410__

↓

Display Alarms Submenu
__420__

↓

Receive User Selected Time
Period for Alarm Mute
__430__

↓

Receive User Selection for
Unmuting the Alarm
__440__

FIG. 4

Detect an Alert Condition
510

No   Is a Routine
Currently Being
Executed?
520   Yes

Trigger Secondary Alert
Notification
530

Yes   Alert
Condition Still
Present?
540   No

Trigger Primary Alert
Notification
570

Deactivate Alarm
560

FIG. 5

ANALYTE MONITORING SYSTEM HAVING AN ALERT

RELATED APPLICATIONS

The present application is a continuation of U.S. patent application Ser. No. 13/953,356 filed Jul. 29, 2013, now U.S. Pat. No. 8,730,058, which is a continuation of U.S. patent application Ser. No. 12/761,387 filed Apr. 15, 2010, now U.S. Pat. No. 8,497,777, which claims priority under 35 U.S.C. §119(e) to U.S. Provisional Patent Application No. 61/169, 654, entitled "Analyte Monitoring System with Alert for Missed Data packet", filed on Apr. 15, 2009 and U.S. Provisional Patent Application No. 61/169,652, entitled "Analyte Monitoring System with Muted Alarm Capability", filed on Apr. 15, 2009, the disclosures of each of which are incorporated herein by reference in their entirety for all purposes.

BACKGROUND

Diabetes Mellitus is an incurable chronic disease in which the body does not produce or properly utilize insulin. Insulin is a hormone produced by the pancreas that regulates blood glucose. In particular, when blood glucose levels rise, e.g., after a meal, insulin lowers the blood glucose levels by facilitating blood glucose to move from the blood into the body cells. Thus, when the pancreas does not produce sufficient insulin (a condition known as Type 1 Diabetes) or does not properly utilize insulin (a condition known as Type II Diabetes), the blood glucose remains in the blood resulting in hyperglycemia or abnormally high blood sugar levels.

People suffering from diabetes often experience long-term complications. Some of these complications include blindness, kidney failure, and nerve damage. Additionally, diabetes is a factor in accelerating cardiovascular diseases such as atherosclerosis (hardening of the arteries), which often leads to stroke, coronary heart disease, and other diseases, which can be life threatening.

The severity of the complications caused by both persistent high glucose levels and blood glucose level fluctuations has provided the impetus to develop diabetes management systems and treatment plans. In this regard, diabetes management plans historically included multiple daily testing of blood glucose levels typically by a finger-stick to draw and test blood. The disadvantage with finger-stick management of diabetes is that the user becomes aware of his blood glucose level only when he performs the finger-stick. Thus, blood glucose trends and blood glucose snapshots over a period of time is unknowable.

More recently, diabetes management has included the implementation of glucose monitoring systems. Glucose monitoring systems have the capability to continuously monitor a user's blood glucose levels. Thus, such systems have the ability to illustrate not only present blood glucose levels but a snapshot of blood glucose levels and blood glucose fluctuations over a period of time. Further, when monitoring the blood glucose levels, the glucose monitoring systems have the capability to output an alert notification to notify the user of an event, such as a hyperglycemic or hypoglycemic event. Although the alert features are a big advantage to managing diabetes, sometimes an alert, such as the loud sounding of an audible alarm, can occur at an inopportune time.

Additionally, the accuracy of continuous glucose monitoring systems depend on the proper and prompt relay of data information about minute to minute glucose levels from a sensor to a receiver component of the system. When the data

information fails to reach the receiver, the lack of glucose data can not only affect the displayed glucose readings to the user, but also provide the user with a false sense of security.

Therefore, a need exists for a user to have the capability to selectively disenable and re-enable alert notification features of a glucose monitoring system for a predetermined period of time and for the analyte monitoring system to sound an alarm or otherwise alert the user to missed data packets so that the user can intervene.

SUMMARY

Embodiments of the present disclosure include analyte monitoring systems including a receiver or data processing component configured to automatically issue a first alert notification when a first predetermined number of consecutive data packets are not received from the sensor/sensor electronics, and automatically issue a second alert notification when a second predetermined number of consecutive data packets are not received by the sensor/sensor electronics. The receiver may be configured to enable a user to disenable alert or alarm notifications that are triggered based on detected events.

In certain embodiments, the receiver has the capability of displaying blood glucose readings related to the received data. The receiver is also configured to output an alert notification based on an event, such as, for example, a hypoglycemic event, a hyperglycemic event, an impending hypoglycemic event, an impending hypoglycemic event, or when a predetermined number of consecutive data packets are not received by the receiver. Additionally, the receiver is configured to provide a user the capability to selectively disenable the alarm for a predetermined time period and also re-enable the alarm prior to elapse of the predetermined time period.

In certain embodiments, the alert can be a visual alert, such as a displayed icon, an audible alert, such as a beep or music, a tactile alert such as a vibration of a system component or a combination thereof. The alert can have multiple modes of notification. In one embodiment, the alert is tri-modal. Thus, the alert can simultaneously include an audible, visual, and tactile notification. In this regard, the receiver can be configured to mute only one or two of the three alarm modes. For the purpose of illustration and not limitation, the audible notification can be muted by the user while the tactile (e.g., vibration) and visual (e.g., icon) notifications are not disenabled. Thus, when an event triggers the alert notification, the user is notified of the event or condition by feeling the vibration and/or seeing the icon.

As explained in greater detail below, the alert notification, or components thereof, can be selectively disenabled for a predetermined amount of time up to a maximum predetermined period of time, such as, for example, twelve hours. In this regard, the receiver can be configured to allow the user to select disenabling the alarm for an entire predetermined period (e.g., two hours, six hours) or alternatively, the selective disenablement of the alarm for the predetermined period can be set in one-hour increments or less.

Embodiments further include a receiver that may be configured such that the alert is incapable of being disenabled for a critical event such as a low glucose level, a decreasing blood glucose trend, a hypoglycemic event, or a blood glucose level above or below a particular threshold level. In this regard, the receiver is capable of allowing a user to disenable the alarm only for non-critical events, such as but not limited to, battery status, sensor life, and the like.

INCORPORATION BY REFERENCE

The following patents, applications and/or publications are incorporated herein by reference for all purposes: U.S. Pat.

Nos. 4,545,382; 4,711,245; 5,262,305; 5,264,104; 5,320,715; 5,509,410; 5,543,326; 5,593,852; 5,601,435; 5,628,890; 5,820,551; 5,822,715; 5,899,855; 5,918,603; 6,071,391; 6,103,033; 6,120,676; 6,121,009; 6,134,461; 6,143,164; 6,144,837; 6,161,095; 6,175,752; 6,270,455; 6,284,478; 6,299,757; 6,338,790; 6,377,894; 6,461,496; 6,503,381; 6,514,460; 6,514,718; 6,540,891; 6,560,471; 6,579,690; 6,591,125; 6,592,745; 6,600,997; 6,605,200; 6,605,201; 6,616,819; 6,618,934; 6,650,471; 6,654,625; 6,676,816; 6,730,200; 6,736,957; 6,746,582; 6,749,740; 6,764,581; 6,773,671; 6,881,551; 6,893,545; 6,932,892; 6,932,894; 6,942,518; 7,167,818; and 7,299,082; U.S. Published Application Nos. 2004/0186365, now U.S. Pat. No. 7,811,231; 2005/0182306, now U.S. Pat. No. 8,771,183; 2007/0056858, now U.S. Pat. No. 8,298,389; 2007/0068807, now U.S. Pat. No. 7,846,311; 2007/0227911, now U.S. Pat. No. 7,887,682; 2007/0233013; 2008/0081977, now U.S. Pat. No. 7,618,369; 2008/0161666; and 2009/0054748, now U.S. Pat. No. 7,885, 698; U.S. patent application Ser. Nos. 12/131,012; 12/242, 823, now U.S. Pat. No. 8,219,173; 12/363,712, now U.S. Pat. No. 8,346,335; 12/495,709; 12/698,124; 12/699,653; 12/699, 844, now U.S. Pat. No. 8,930,203; and 12/714,439 and U.S. Provisional Application Nos. 61/230,686 and 61/227,967.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a block diagram of an analyte monitoring system for practicing one or more embodiments of the present disclosure;

FIG. 2 is a flowchart illustrating a method for detecting a missed data packet and issuing an alert in accordance with one embodiment of the present disclosure;

FIG. 3 is a flowchart illustrating a concurrent passive notification routine in a receiver of the analyte monitoring system in accordance with one embodiment of the present disclosure;

FIG. 4 is a flowchart illustrating an alarm notification disenabling and re-enabling routine in a receiver of the analyte monitoring system in accordance with one embodiment of the present disclosure; and

FIG. 5 is a flowchart illustrating a method for detecting an alert condition in accordance with one embodiment of the present disclosure.

DETAILED DESCRIPTION

Reference will now be made in detail to the embodiments of the present disclosure, examples of which are illustrated in the accompanying figures. As such, various aspects will be described in conjunction with the detailed description of the device. However, there is no intent to limit the scope of the present disclosure to the specific embodiments described herein.

Generally, the present disclosure is directed to an analyte monitoring system comprising a sensor operatively in contact with an analyte to be monitored, a transmitter operatively coupled to the sensor and a receiver for receiving data information from the transmitter relating to the concentration or amount of the analyte. The transmitter, which is operatively coupled to the sensor receives the raw data signals and processes the signals into a data packet. Each data packet comprises three values, the current analyte value and the two immediately preceding analyte values. The data packet is transmitted to a receiver component, which is configured to issue an alert when at least two consecutive data packets are missed or otherwise not received from the transmitter.

The receiver includes a display unit for displaying the analyte amount or concentration (e.g., mg/dL) to a user. In

this regard, the term "user" includes but is not limited to the actual subject being monitored. For example, it is contemplated that the "user" could be a caretaker for the monitored subject. The analyte monitoring system is capable of continuously or intermittently monitoring an analyte in a biological fluid. In this regard, the biological fluid can be blood, interstitial fluid, urine or another fluid containing the analyte to be monitored.

The analyte monitoring system is configured to provide a user the capability to selectively disenable an alarm notification of the occurrence of an event for a predetermined period of time and selectively re-enable the alarm prior to elapse of the predetermined period of time. In certain embodiments, the event which triggers an alarm output notification can include, for example, analyte events, data loss events and system events.

In one embodiment, the analyte monitoring system is a continuous glucose monitoring system. In this regard, the analyte events are glucose events and include but are not limited to low glucose levels (e.g., when single or continuous glucose level is below a threshold), high glucose levels (e.g, when a single or continuous glucose level is above a threshold), decreasing glucose trend or increasing glucose trend. For the purpose of illustration, there are multiple ways to configure an analyte monitoring system to output an alarm notification based on an increasing or decreasing glucose trend. For example, the trend information can be based on multiple glucose datapoints in which the rate of change indicates a trend, or alternatively, a projected trend information can be based on predicting or projecting that the glucose level will exceed a particular threshold value based on a current trend.

Data loss events include but are not limited to a disconnection between the receiver and transmitter, improper insertion or implantation of the sensor, expired calibration, sensor error (e.g., not being able to calculate glucose), transmitter error (e.g., high work current noise, persistent skin temperature out of range, etc), or receiver error (e.g., RF data packet timing synchronization between CGE and UI processor was lost). System events include but are not limited to battery status (e.g., one week of battery remains, replacement battery needed), failed calibration, calibration request, early signal attenuation, acceleration of most recent valid data is too large, high signal saturation detected by transmitter, sensitivity is too high or too low, outlier detected, lost preferences, RF connection has been down for a predetermined time period (e.g., five minutes), log data corrupted, detected insertion transient, and sensor removal.

FIG. 1 illustrates an analyte monitoring system 100 of the present disclosure. As shown in FIG. 1, the analyte monitoring system 100 includes sensor 101 operatively coupled to a transmitter unit 102. The transmitter unit is in operative communication with a primary receiver 104 via communication path 103. In certain embodiments, the analyte monitoring system can further include a secondary receiver 106. In certain embodiments, each of the receivers 104, 106 may be configured to transmit data information to a remote processor 105.

In certain embodiments, the sensor 101 of the analyte monitoring system 100 includes a substrate, a working electrode, a counter electrode, and a reference electrode. The working electrode, the counter electrode and the reference electrode are formed from conductive material. Examples include, but are not limited to, gold, carbon, Ag/Cl, and the like. In one embodiment, the substrate and electrodes are arranged in a stacked orientation, such as when insulating material is disposed between the electrodes.

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A sensing layer, which includes at least one immobilized enzyme and an immobilized mediator agent is disposed on at least a portion of at least the working electrode. In one embodiment, the immobilized molecule is glucose oxidase and the mediator agent includes a noble metal, such as but not limited to osmium. The sensor can further include a biocompatible layer. The biocompatible layer is disposed on at least a portion of the sensing layer. In one embodiment, the biocompatible membrane and the sensing layer are partially bonded to define a heterogeneous multilayer.

In certain embodiments, the sensor **101** is in operative contact with an analyte. The term "analyte" refers to a substance or chemical constituent in a biological fluid, such as for example, blood or interstitial fluid. For example and not limitation, the analyte can be glucose, lactate, acetyl choline, amylase, bilirubin, cholesterol, chorionic gonadotropin, creatine kinase (e.g., CK-MB), creatine, DNA, fructosamine, glucose, glutamine, growth hormones, hormones, ketones, peroxide, prostate-specific antigen, prothrombin, RNA, thyroid stimulating hormone, and troponin. However, other analytes can be monitored as would be understood by one of ordinary skill in the art.

In some embodiments, sensor **101** is implantable into a subject's body for a period of time (e.g., three to five days) to contact and monitor an analyte present in a biological fluid. In this regard, the sensor can be disposed in a subject at a variety of sites, including intramuscularly, transcutaneously, intravascularly, or in a body cavity. Sensor **101** is configured to generate data signals relative to the amount or concentration of the analyte to be monitored.

Sensor **101** operatively contacts the analyte to be measured and generates raw data signals relating to the amount or concentration of the analyte detected. In certain embodiments, transmitter **102** is operatively coupled to sensor **101** and obtains information relating to the data signals from sensor **101**. The transmitter **102** processes the data signals (e.g., encodes signals) received from the sensor **101** into a data packet. The data packet comprises a current analyte value and the two immediately preceding analyte values. The data packets are transmitted to receiver **104** via radiofrequency communications link **103**.

In one embodiment, the transmitter **102** also includes a temperature sensor. In this regard, the temperature sensor measures an ambient temperature of the system. Alternatively, the transmitter can be configured to be worn on the skin of a user. Thus, the temperature sensor measures the skin temperature of the user.

The analyte monitoring system **100** also includes a receiver **104**, which accepts analyte values from the transmitter over a communication link **103**. Communication link **103** may be a wired communication link or a wireless communication link utilizing protocols including, but not limited to, radio frequency (RF), radio frequency identification (RFID), infrared (IR) or Bluetooth® communication protocols. In certain embodiments, the receiver **104** comprises an input device for receiving user input, a processor, and a computer readable medium for storing data relating to the operation of the analyte monitoring device and software, which when executed by the processor, determines whether an alert condition exists, whether the alert is disenabled or whether a data packet from the transmitter is not received or otherwise missed by the receiver. Thus, the receiver is configured to expect a data packet and issue an alert when an expected data packet is not received. Furthermore, the receiver may also include a memory that is capable of logging analyte concentration or

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analyte amount values. The receiver **104** may also allow a user to erase the logged analyte concentration or amount values.

As will be discussed in further detail below, the receiver **104** is configured to expect a data packet from the transmitter **102** at predetermined time intervals, such as, for example, every five minutes or less. In another embodiment, the receiver **104** is configured to expect a data packet from the transmitter **102** every minute or less. Still yet other embodiments provide that the user may select how often the receiver **104** should expect a data packet from the transmitter **102**. Additionally, it is contemplated that data packets may be expected by the receiver **104** at different times depending on a condition of the user. For example, when a critical event or semi-critical event is detected, the receiver **104** may expect data packets more frequently than when continuous glucose readings are more stable.

In certain embodiments, the receiver **104** alerts the user to reconnect the receiver or the transmitter if a predetermined number of consecutive data packets are not received by the receiver **104**. For example, if three consecutive data packets are not received by the receiver, an alert is issued. The alert can be an auditory alert, a visual alert, a tactile alert, or a combination thereof. Still yet other embodiments provide that the alert can be a continuous alert if the receiver fails to receive more than five consecutive data packets from the transmitter. The analyte monitoring system can be configured to automatically disengage an alert notifying a user of non-receipt of data packets upon the subsequent receipt of a data packet.

The receiver **104** uses the data to compute an analyte concentration or amount. The receiver **104** can be configured to display glucose values. In one embodiment, the receiver **104** includes two interconnected central processors. In one embodiment, one central processor is configured for displaying images on a display screen such as an LCD screen, user input and output functionality, as well as handling the user-interface of the receiver **104**. The second central processor may be configured for test strip measurements, such as calibration, radiofrequency link radio interface, and a real time clock.

As discussed above, the receiver **104** also includes a display for displaying an indication of the level of the measured analyte as well as notifications of alerts. In one embodiment, the display unit may be separate from the receiver. In the alternative, the display unit can be coupled to the receiver. In some embodiments, the receiver and/or display unit may include a variety of components, such as, for example, a transmitter, an analyzer, a data storage unit, a watchdog circuit, an input device, a power supply, a clock, a lamp, a pager, a telephone interface, a computer interface, an alarm or alarm system, a radio, and a calibration unit. In some embodiments, the receiver **104** provides a display screen for a line graph that plots logged analyte values versus time.

FIG. **2** is a flowchart illustrating a method for detecting a missed data packet and issuing an alert in accordance with one embodiment of the present disclosure. As discussed above, a receiver, such as receiver **104** of the analyte monitoring system **100** of FIG. **1**, may be configured to expect a data packet from a transmitter, such as transmitter **102** (FIG. **1**) at regular time intervals. In certain embodiments, the time intervals may be every five minutes. In alternative embodiments, the time interval may be every minute. Still yet other embodiments provide that the interval may automatically change based on a detected condition of a user, a time of day, or a user initiated event, such as, for example, exercising, eating a meal, etc. Regardless of the time interval used, the

receiver may be configured to anticipate a data packet at the selected or predetermined time interval.

Accordingly, in certain embodiments, as shown in FIG. 2, a processor of the receiver 104 is configured to determine whether data packets are received from the transmitter 102 at predetermined time intervals. In certain embodiments, the predetermined time intervals may be user selectable. In other embodiments, the predetermined time intervals are based on a monitored condition of a user. For example, if a rate of change of an analyte level of the user is within a predetermined threshold, the predetermined time interval may be three minutes. If the rate of change of the user's analyte level exceeds the threshold, the predetermined time interval may be one minute. If the processor determines that the receiver 104 has not received a data packet as expected (210) the receiver may be configured to attempt to recapture data packets automatically, requiring no user intervention. For example, the receiver 104 may issue a command to the transmitter 102 requesting that the transmitter 102 resend the last data packet. When the request is received, the transmitter 102 resends the last data packet via the communication link 103. If the processor detects that a single expected data packet was not received, the processor does not issue a command to generate an alert and the processor resumes detecting an arrival of a subsequent data packet.

If however, the processor detects that a first predetermined number (220) (e.g., two) of consecutive expected data packets were not received by the receiver 104, the processor issues a command to generate an alert notification (230). In certain embodiments, the alert notification may be a single alert or a series of alerts. Additionally, the alert notification may be an icon displayed on a display screen of the device, flashing lights, a warning screen and the like. Alternatively, the alert notification may be an auditory notification or a vibratory notification or a combination thereof.

In certain embodiments, the type of alert notifications may be user selectable. Additionally, the alerts may be color coded or have different volumes or vibration speeds based on a severity of the alert condition. For example, if the notification is a warning screen having text, the color of the text, a border of the screen or a background of text may be color coded based on number of consecutive data packets missed. In certain embodiments where the alert is an auditory alert, the tone and/or volume of the auditory alert may be user selectable. For example, if two data packets in a row were missed, two low volume beeps may sound. If however, three data packets in a row are missed, the volume may change to medium level and three beeps may sound. In embodiments, a user may select a tone, the length of the tone and the volume of the tone for each auditory notification. Finally, if the alert is a vibratory alert, the user may select the duration and/or frequency of the vibration.

Referring back to FIG. 2, once the alert is issued, the receiver 104 is configured to wait for a predetermined time interval, such as, for example, one minute, before checking the receipt of the next expected data packet. Although a one minute time interval is specifically mentioned, it is contemplated that the predetermined time interval may be more or less than one minute.

In certain embodiments, the predetermined time interval may automatically adjust based on the severity of the alert, such as, for example, the number of consecutive data packets not received. Thus, the higher the number of consecutive data packets not received, the smaller the predetermined time interval. Alternatively, the predetermined time interval may correspond to the interval at which the data packets are expected to arrive at the receiver 104. Thus, if data packets are

expected to arrive at the receiver 104 every two minutes, the predetermined time interval is two minutes. Still yet other embodiments provide that the predetermined time interval corresponds to a fraction of time of the expected data packet arrival at the receiver 104. Thus, if a data packet is expected every five minutes, the predetermined time is two and a half minutes or some other fraction of time.

If the first predetermined number of consecutive data packets has not been received and there has been no user action to remedy the loss of the data packets, the processor of the receiver 104 detects whether a second predetermined amount of consecutive data packets has not been received. In certain embodiments, the count of consecutive data packets not received is not reset until at least one data packet is received. Other embodiments provide that the count of the number of consecutive data packets not received is reset by the processor after an alarm is acknowledged. If it is determined that a second predetermined number of consecutive data packets has not been received (240), the processor issues a command to generate a secondary alert (250) to notify the user to reconnect the receiver 104 and/or transmitter 102. For example, if five consecutive data packet are not received, an alert can be issued, by enabling an "RF MISSED A FEW" message or any other message or indication to indicate multiple data packets have been missed. As discussed above, the alert may be auditory, visual tactile or a combination thereof. If a user does not respond to the alert after a predetermined amount of time, the receiver 104 waits for a predetermined amount (280) of time before determining whether a subsequent data packet is received. In certain embodiments, because a second predetermined number of consecutive data packets were not received, the predetermined amount of time (280) may be reduced accordingly. For example, if five consecutive data packets were missed, the predetermined amount of time may be reduced from two minutes to one minute. Thus, as the number of consecutive data packets that are missed increases, the predetermined amount of time before checking the receipt of the next expected data packet is reduced.

If the processor of the receiver 104 detects a third predetermined number of consecutive expected data packets are not received by the receiver (260), the processor of the receiver 104 is configured to issue an alert (270), such as, for example, a persistent alarm that notifies the user to reconnect the receiver 104 to the transmitter 102. In certain embodiments, the persistent alert may not be mutable. Other embodiments provide that a user may silence or "snooze" the alert for a small amount of time. However, once the time period expires, the alert is triggered again. Other embodiments provide that if the alert is silenced repeatedly, the ability to silence the alarm is deactivated. Still yet other embodiments provide that the volume of the alert increase after each time the alert is snoozed or silenced. In certain embodiments, when the third predetermined number of consecutive alerts has been reached or exceeded, other alert notifications may be inactive. If the alert condition is not addressed by the user within a specified amount of time, the receiver 104 waits for the predetermined amount of time (280) before checking the receipt of the next expected data packet. If a data packet is not received, the alert is triggered.

In certain embodiments, regardless of how many consecutive data packets have been missed, the receiver 104 can be configured to de-assert (290) any issued alert after it successfully receives the next expected data packet subsequent to one or consecutive missed data packets. It will be recognized by one skilled in the art that the receiver can be configured to issue an alert and de-assert an alert based on a different number of consecutive missed data packets. For example, if

five consecutive data packets have been missed and an alert has been issued, the receiver may be configured to de-assert the alert only when a predetermined number of consecutive data packets (e.g., three) have been received without interruption.

As discussed above, the alert issued by the receiver may contain one or more individual alarms. In one embodiment, the alert is a tri-modal alarm, which includes a visual notification (e.g., icon, message, or flashing lights), tactile notification (e.g. vibration) and audible (e.g., beep or ring tones, or music). Other sensory-stimulating alarm systems may be used including alerts which heat, cool, or produce a mild electrical shock when triggered.

In another aspect, the analyte monitoring system 100 (FIG. 1) includes an alarm notification feature to alert or warn a user of an event, such as, for example, a critical event like a potentially detrimental condition. For example, if glucose is the analyte, the alarm may notify a user of hypoglycemia, hyperglycemia, impending hypoglycemia, and/or impending hyperglycemia. In this regard, the alarm is configured such that when the data from the sensor 101 reaches or exceeds a threshold value, it outputs an alarm notification. Some non-limiting examples of threshold values for blood glucose levels are about 60, 70, or 80 mg/dL for hypoglycemia, about 70, 80, or 90 mg/dL for impending hypoglycemia, about 130, 150, 175, 200, 225, 250, or 275 mg/dL for impending hyperglycemia, and about 150, 175, 200, 225, 250, 275, or 300 mg/dL for hyperglycemia.

The threshold values that are designed into the alarm can correspond to interstitial fluid glucose concentrations or electrode measurements (e.g., current values or voltage values obtained by conversion of current measurements) that correlate to the above-mentioned blood glucose levels. The analyte monitor system may be configured so that the threshold levels for these or any other conditions may be programmable by the patient, caregiver or medical professional.

In certain embodiments, a threshold value is exceeded if a datapoint, such as a glucose datapoint, has a value that is above or below the threshold value indicating an impending or particular condition, such as hypoglycemia or hyperglycemia. For the purpose of illustration, a datapoint correlating to a glucose level of 200 mg/dL exceeds the threshold value (180 mg/dL) for hyperglycemia, and indicates that the monitored subject has already entered a hyperglycemic state. As another example, a datapoint correlating to a glucose level of 65 mg/dL exceeds a threshold value (70 mg/dL) for hypoglycemia and indicates that the monitored subject entered a hypoglycemic state. However, a datapoint correlating to a glucose level of 75 mg/dL would not exceed the same threshold value for hypoglycemia because the datapoint does not indicate a hypoglycemic state as defined by the predetermined threshold value.

The analyte monitoring system can also be configured to activate an alarm, such as by embedded software, if the sensor readings indicate that a value is beyond a measurement range of the sensor 101. For glucose, the physiologically relevant measurement range is typically about 50 to 250 mg/dL, preferably about 40 to 300 mg/dL and ideally 30 to 400 mg/dL, of glucose in the interstitial fluid. The alarm may also, or alternatively, be activated when the rate of change or acceleration of the rate of change in the analyte level increases or decreases at or above a predetermined threshold rate or acceleration. For example, in the case of a subcutaneous glucose monitor, the alarm system might be activated if the rate of change in glucose concentration exceeds a threshold value which might indicate that a hyperglycemic or hypoglycemic condition is likely to occur.

The alarm may be configured to output a notification if a single data point meets or exceeds a particular threshold value. Alternatively, the alarm may be configured to output a notification if a predetermined number of datapoints spanning a predetermined amount of time meet or exceed the threshold value. As another alternative, an alarm notification may be output only when the datapoints spanning a predetermined amount of time have an average value which meets or exceeds the threshold value. Each condition that can trigger an alarm may have a different alarm activation condition. In addition, the alarm activation condition may change depending on current conditions (e.g., an indication of impending hyperglycemia may alter the number of datapoints or the amount of time that is tested to determine hyperglycemia).

FIG. 3 is a flowchart illustrating a concurrent passive notification routine in a receiver of the analyte monitoring system according to one embodiment of the present disclosure. In certain embodiments, the analyte monitoring system, such as the analyte monitoring system 100 of FIG. 1, can include a concurrent passive notification routine. At the start of the concurrent passive notification routine, a processor of the receiver 104 (FIG. 1) executes a predetermined routine (310) for a time period until the routine is completed. Such routines may include blood glucose tests, calibration routines, medication dosage adjustments, such as a bolus dose or an update to a basal regiment. Other embodiments provide that the routine is a user initiated routine such as viewing various display screens on the receiver, updating system preferences, manually entering data such as, for example, event data, and the like. During the execution of the predetermined routine, an alarm condition is detected (320) by the processor of the receiver 104. In certain embodiments, the alarm condition may be triggered by a datapoint exceeding a threshold. When the alarm condition is detected, the processor causes a first indication associated with the detected alarm condition to be output concurrent with the execution of the predetermined routine (330).

In accordance with one embodiment, when the predetermined routine is being executed and an alarm condition is detected, a notification associated with the detected alarm condition is provided to the user without disrupting the routine. In certain embodiments, the alarm notification may be an audible beep or noise, a backlight indicator, an icon, a modification in any display item feature such as a border around a field that flashes, or a text output on the user interface display or any other suitable output indication to alert the user of the detected alarm condition substantially in real time, but which does not disrupt the ongoing routine. For example, when the predetermined routine is being executed, an icon or other visual indicator may be displayed in a corner of the current display screen of the predetermined routine to indicate that an alarm condition is detected.

Upon termination of the predetermined routine (340), another output or second indication associated with the detected alarm condition is output or displayed. In certain embodiments, the processor of the receiver 104 may detect that the predetermined routine has terminated and subsequently output the second indication. For example, if the predetermined routine is a calibration routine, the processor detects when the calibration is complete. In other embodiments, such as, for example, user initiated routines, the termination of the routine may be determined or detected based on a user activated event via the user interface. In certain embodiments, the second indication associated with the detected alarm condition is sounded and/or displayed more prominently. For example, and as described above, as the predetermined routine is executing, the alarm may be a soft

tone or sound, a discretely displayed icon or textual message, a slight color change to the background of the current display screen and the like. However, when the routine is finished executing, the alarm is sounded or displayed prominently to indicate the detection of the alert condition.

In a further aspect, the user interface notification feature associated with the detected alarm condition is output to the user only upon the completion of an ongoing routine which was in the process of being executed when the alarm condition was detected.

In another aspect, the receiver is configured to provide a user the capability to disenable the alarm notification output for a predetermined time period and to re-enable the alarm notification prior to termination of the predetermined time period. Thus, if the user is running a routine or a series of routines that will take a substantial amount of time, the user may select to disenable the output of the first alarm and/or the output of the second alarm for a predetermined amount of time. In one embodiment, a glucose monitoring system is configured to allow the user to disenable an alarm notification, via a user interface, only if the user's blood glucose level is within predetermined parameters, such as for example, between about 60 and 139 mg/dL.

As discussed above, the alarm may contain one or more individual alarms. In one embodiment, the alarm is a tri-modal alarm, which includes a visual notification (e.g., icon or flashing lights), tactile notification (e.g. vibration) and audible (e.g., beep or ring tones, or music). Other sensory-stimulating alarm systems may be used including alarms which heat, cool, or produce a mild electrical shock when triggered. In some embodiments, auditory alarms have different tone, note, or volume indicating different conditions. For example, a high note might indicate hyperglycemia and a low note might indicate hypoglycemia. Visual alarms may use a difference in color, brightness to indicate different conditions or severity levels. In some embodiments, an auditory alarm is configured so that the volume of the alarm increases over time until the alarm is deactivated.

In some embodiments, the alarm may be automatically deactivated after a predetermined time period. In other embodiments, the alarm may be configured to deactivate when the data no longer indicates that the condition which triggered the alarm exists. In these embodiments, the alarm may be deactivated when a single data point indicates that the condition no longer exists or, alternatively, the alarm may be deactivated only after a predetermined number of datapoints or an average of the datapoints obtained over a given period of time indicate that the condition no longer exists.

Other embodiments provide that the alarm may be deactivated manually by a user. In these embodiments, a switch is provided and when actuated, the alarm is turned off. The switch may be operatively engaged (or disengaged depending on the configuration of the switch) by, for example, operating an actuator on sensor **101** or the receiver/display unit **104**. In some cases, an actuator may be provided on two or more units including the sensor **101**, transmitter **102**, primary receiver **104**, secondary receiver **106**, or elsewhere, any of which may be actuated to deactivate the alarm.

A variety of switches may be used including, for example, a mechanical switch, a reed switch, a Hall effect switch, a Gigantic Magnetic Ratio (GMR) switch (the resistance of the GMR switch is magnetic field dependent) and the like. Preferably, the actuator used to operatively engage (or disengage) the switch is placed on the sensor **101** and configured so that no water can flow around the button and into the housing. One example of such a button is a flexible conducting strip that is completely covered by a flexible polymeric or plastic coating

integral to the housing. In an open position the flexible conducting strip is bowed and bulges away from the housing. When depressed by the patient or another person, the flexible conducting strip is pushed directly toward a metal contact and completes the circuit to shut off the alarm.

In instances when a reed or GMR switch is used, a flexible actuator containing a magnetic material, such as a permanent magnet or an electromagnet may be used to deactivate the alarm. In such embodiments, the flexible actuator may bulge away from the housing. Thus, when reed or GMR switch is activated (to deactivate the alarm) by depressing the flexible actuator, the magnetic material is brought closer to the switch which causes an increase in the magnetic field within the switch and the alarm is deactivated.

FIG. **4** is a flowchart illustrating an alarm notification disenabling and re-enabling routine in a receiver of the analyte monitoring system in accordance with one embodiment of the present disclosure. In certain embodiments and as described below, the analyte monitoring system **100** (FIG. **1**) provides a user with the capability to disenable the alarm prior to activation of an alarm notification by a particular event, such as a single data point exceeding a threshold, a hyperglycemic state, a decreasing trend of analyte concentrations. In this regard, a user can access the alarms menu to disenable and re-enable the alarm from a user interface of analyte monitoring system.

The routine for disenabling and re-enabling alarm notifications begins when a user is presented with a user interface on a receiver **104** (FIG. **1**) and the user makes a selection of one of the options thereon (**410**). In certain embodiments, the user interface includes a main menu having a plurality of selection options. Nonlimiting examples of the selection options may include "Glucose," "Alarms," "Reports," "System," and "Add Event." A user may navigate the list of options and select one of the options using an actuator disposed on the receiver **104**, such as, for example, a jog wheel, arrow keys on the receiver, a touch sensitive portion of the display and the like. When a processor of the receiver **104** detects user selection of the "Alarms" option, a submenu for the "Alarms" option is displayed (**420**). In certain embodiments, the submenu of the "Alarms" option that includes an alarm menu for disenabling and/or muting alarms is displayed only if the alarm notification is not already disenabled (for example audible alarm muted). Alternatively, the submenu user interface that includes an alarm menu for disenabling and/or muting alarms is displayed regardless of whether alarm notifications are disenabled. Still yet other embodiments provide that selection of the submenu will only display alarms that can be muted or disenabled.

When the mute alarm option is selected from user menu the receiver displays a user interface that allows a user to select a predetermined period of time for disenablement or muting of the alarm notification (**430**). In embodiments, user selection is enabled using an actuator disposed on the receiver **104**. Selectable predetermined periods can be twelve or less hours. Further, the predetermined time for more than one hour can be by hourly increments. In still yet further embodiments, when a user desires to re-enable the alarm notification, the user interface of the receiver **104** provides a display screen with the option to re-enable the alarm notification feature. In this regard, the user interface provides a menu selection to enable the user to un-mute the alarm notification (**440**). In certain embodiments, the user interface for alarm re-enablement only shows alarms which have been previously disenabled and/or muted.

If desired, the display screen of receiver **104** is configured to blank the user interface if no selection is made in a prede-

termined period of time. For example, the receiver **104** can be configured to blank or fade to black within twenty or more seconds if no selection is made. Other embodiments provide that if a user selection is not made in a predetermined time period, the user is returned to the main menu screen.

In one embodiment, an icon is displayed on the receiver display to indicate alarms are disenabled and/or muted. In some embodiments, the user is allowed to turn off low and high glucose alarms only if the user turns off each alarm mode individually.

FIG. **5** is a flowchart illustrating a method for detecting an alert condition in accordance with one embodiment of the present disclosure. At the start of the routine, a processor of the receiver **104** (FIG. **1**) detects an alert condition (**510**). In embodiments, the alert condition may be detected because of a critical event such as a low glucose level of a user, a decreasing blood glucose trend of the user, a hypoglycemic event, or a blood glucose level above or below a particular threshold level. In other embodiments, the detected alert condition may correspond to non-critical such as, for example, low battery status or low sensor life.

When an alert condition is detected, the processor determines whether a routine is currently being executed (**520**). Such routines may include blood glucose tests, calibration routines, and medication dosage adjustments, such as a bolus dose or an update to a basal regiment. Other embodiments provide that the routine is a user initiated routine such as viewing various display screens on the receiver **104**, updating system preferences, or manually entering data into the receiver.

If the processor determines that a routine is not currently being executed, such as, for example, by detecting an idle state of the receiver, the processor issues a command to generate a primary alert notification (**570**). In one embodiment, the alert notification may include a visual notification (e.g., icon, message, or flashing lights), a tactile notification (e.g. vibration), an audible notification (e.g., beep or ring tones, or music) or a combination thereof.

If the processor determines that a routine is currently being executed, the processor of the receiver **104** issues a command to generate a secondary alert notification (**530**). In embodiments, the secondary alert notification is displayed or otherwise activated so as to not disrupt the routine that is currently being executed. Thus, in certain embodiments, the alarm notification may be an audible beep or noise, a backlight indicator, an icon, a modification in any display item feature such as a border around a field that flashes, or a text output on the user interface display that may be output substantially simultaneously with the routine.

After the secondary alert is generated by the processor, the processor determines whether the condition that triggered the alarm is still present (**540**). For example, if a low battery triggered the alert condition, the processor determines whether the battery has been recharged or is currently recharging. If the alert condition was triggered because a blood glucose level was above or below a particular threshold, the processor determines whether a recent blood glucose level reading is within the predetermined threshold. If it is determined that the condition that triggered the alert no longer exists, the processor issues a command to deactivate the alarm (**560**).

If however, it is determined that the condition that triggered the alert still exists, the processor once again determines whether the routine is currently being executed (**520**). If it is determined that the routine is no longer being executed, the processor issues a command to trigger the primary alert notification (**570**) as described above. However, if it is determined

that the routine is no longer being executed and the condition that triggered the alert no longer exists, the processor issues a command to deactivate any alarms that may still be active.

The various embodiments of detecting missed data packets, issuing alerts, and disenabling and enabling the alerts can be implemented in the receiver which comprises a processor, and a computer readable medium for storing data relating to the operation of the analyte monitoring device and software, which when executed by the processor, determines whether a data packet from the transmitter is not received, or otherwise missed by the receiver, and whether to issue an alert to the user. Thus, the receiver is configured to expect a data packet and issue an alert when an expected data packet is not received.

In one embodiment, an analyte monitoring system includes a sensor in operative contact with an analyte, the sensor adapted to generate a data signal associated with an amount or concentration of the analyte; a transmitter operatively coupled to the sensor and adapted to process the raw data signal generated by the sensor to define a data packet, wherein the data packet comprises a current analyte value and the previous two analyte values; and a receiver operatively linked to the transmitter and capable of receiving the data packet from the transmitter, wherein the receiver is configured to alert a user if at least two consecutive data packets are not received by the receiver.

In another embodiment, the receiver receives the data packet from the transmitter via a radio-frequency communications link.

Further embodiments provide that the alert is a visual alert such as, for example, an icon.

In an embodiment, the alert is an audible alert such as a beep, a tone or music.

In still yet other embodiments, the alert is a tactile alert such as, for example, a vibration of a component of the analyte monitoring system.

Embodiments also include configurations where the receiver alerts the user to reconnect the receiver or the transmitter if more than two consecutive data packets are not received by the receiver.

In certain embodiments, the receiver is configured to expect a data packet from the transmitter every five minutes or less or every minute or less.

In one aspect, the alert automatically disengages when a data packet is received by the receiver subsequent to non-receipt of an earlier data packet.

In another aspect, the alert is a continuous alert if the receiver fails to receive more than five consecutive data packets from the transmitter.

In certain embodiments, the analyte is glucose, and the analyte monitoring system is a continuous glucose monitoring system.

Still yet other embodiments provide that the receiver is wirelessly linked to a data management host.

In other embodiments, the sensor comprises a substrate, a working electrode, a counter electrode, and a reference electrode arranged in a stacked orientation, and further wherein each of the electrodes is formed from a conductive material.

In another embodiment an analyte monitoring system includes a sensor in operative contact with an analyte, the sensor adapted to generate a data signal associated with an amount or concentration of the analyte; a transmitter coupled to the sensor and adapted to process the data signal generated by the sensor; and a receiver capable of receiving the processed data signal and outputting an alarm notification based on an event, wherein the receiver is configured to allow a user to disenable the alarm notification for a predetermined time

period and to re-enable the alarm notification prior to elapse of the predetermined time period.

In one embodiment, the alarm is a tri-modal alarm and includes an audible alarm, a visual alarm and a tactile alarm.

In yet another embodiment, the receiver is adapted to disenable only one mode of the alarm.

In one aspect, the disenabled alarm notification is muting an audible alarm.

In another aspect, the predetermined time is about one to twelve hours.

In yet another aspect, the predetermined period is more than one hour and further the mute is set in one hour increments for the entire predetermined period.

Embodiments provide that the receiver is capable of displaying an icon indicator when the alarm is muted.

Other embodiments provide that the alarm is incapable of being disenabled by a user for a critical event such as, for example, a low glucose event.

In one embodiment, the event is a system or data loss event.

Still yet other embodiments provide that the sensor further includes insulating material disposed between the electrodes.

Embodiments also provide that a sensing layer is disposed on at least a portion of at least the working electrode, the sensing layer including at least one immobilized enzyme and an immobilized mediator agent.

In certain embodiments, the sensor further includes a biocompatible membrane disposed on at least a portion of the sensing layer.

Embodiments provide that the biocompatible membrane is at least partially bonded to the sensing layer to define a heterogeneous multilayer.

In an embodiment, the transmitter is worn on the body of a user.

In an embodiment, the transmitter is a temperature sensor.

Embodiments also provide that the receiver has a memory capable logging analyte concentration or amount values.

Still further embodiments provide that the receiver is configured to allow a user to erase the logged analyte concentration or amount values.

Various other modifications and alterations in the structure and method of operation of this disclosure will be apparent to those skilled in the art without departing from the scope and spirit of the embodiments of the present disclosure. Although the present disclosure has been described in connection with particular embodiments, it should be understood that the present disclosure as claimed should not be unduly limited to such particular embodiments. It is intended that the following claims define the scope of the present disclosure and that structures and methods within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. An analyte monitoring system, comprising:
sensor electronics operatively coupled to an analyte sensor in fluid contact with interstitial fluid and configured to generate a data packet including a current analyte value and a plurality of prior analyte values; and
a data receiver in signal communication with the sensor electronics and configured to receive the data packet from the sensor electronics, the data receiver further configured to automatically output a first alert notification when a first predetermined number of data packets is not received by the data receiver, and automatically output a second alert notification when a second predetermined number of data packets is not received by the data receiver.

2. The analyte monitoring system of claim 1, wherein the second alert notification is different than the first alert notification.

3. The analyte monitoring system of claim 1, wherein each of the first alert notification and the second alert notification is one of an auditory notification, a tactile notification or a visual notification.

4. The analyte monitoring system of claim 1, wherein the data receiver is configured to automatically output the first alert notification when a first predetermined number of consecutive data packets is not received by the data receiver, and automatically output the second alert notification when a second predetermined number of consecutive data packets is not received by the data receiver.

5. A method, comprising:
outputting a first alert notification type when a first predetermined number of data packets is not received; and
outputting a second alert notification type when a second predetermined number of data packets is not received, wherein the first alert notification type is output at a first predetermined output level and wherein the second alert notification type is output at a second predetermined output level.

6. The method of claim 5, further comprising anticipating receipt of a subsequent data packet at a first predetermined period of time when the first predetermined number of data packets is not received.

7. The method of claim 6, wherein the first predetermined period of time is based, at least in part, on the first predetermined number of data packets that is not received.

8. The method of claim 5, further comprising anticipating receipt of a subsequent data packet at a second predetermined period of time when the second predetermined number of data packets is not received.

9. The method of claim 8, wherein the second predetermined period of time is based, at least in part, on the second predetermined number of data packets that is not received.

10. The method of claim 5, wherein the first alert notification type is disabled when a subsequent data packet is received.

11. The method of claim 5, wherein the first alert notification type is disabled when a predetermined number of subsequent data packets is received.

12. The method of claim 5, wherein the second alert notification type is disabled when a subsequent data packet is received.

13. The method of claim 5, wherein the second alert notification type is disabled when a predetermined number of subsequent data packets is received.

14. The method of claim 5, further comprising selectively disabling at least one of the first alert notification type or the second alert notification type.

15. The method of claim 5, wherein the first alert notification type is output when a first predetermined number of consecutive data packets is not received, and further, wherein the second alert notification type is output when a second predetermined number of consecutive data packets is not received.

16. A method, comprising:
detecting an occurrence of a predetermined routine;
outputting a first notification of an alarm condition at a first output level when a first number of data packets is not received; and
outputting a second notification of the alarm condition at a second output level when termination of the predetermined routine is detected.

17. The method of claim **16**, wherein the first notification of the alarm condition is output concurrently with the occurrence of the predetermined routine.

18. The method of claim **16**, further comprising disabling at least one of the first notification and the second notification.

19. The method of claim **16**, wherein the predetermined routine is one of a blood glucose test, a calibration routine, or a medication dosage adjustment.

20. The method of claim **16**, wherein detecting the occurrence of the alarm condition includes detecting the alarm condition when a first predetermined number of consecutive data packets is not received.

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